

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

NOVO NORDISK A/S and  
NOVO NORDISK, INC.,

Plaintiffs,

-vs-

Case No. 05-40188  
Hon: AVERN COHN

CARACO PHARMACEUTICAL  
LABORATORIES, LTD. and  
SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

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**MEMORANDUM**

**I. INTRODUCTION**

This is a patent case. The background of the case can be found in Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd., 601 F.3d 1359 (Fed. Cir. 2010). Currently, Caraco is challenging the validity and enforceability of Novo's '358 patent on grounds of obviousness and inequitable conduct.

Now before the Court is Novo's Memorandum Regarding the Relevant Date for "Prior Art" References. Novo says that the relevant date is January 1, 1996, the date of invention under 35 U.S.C. §§ 102(a) and 104(a) and objects to Caraco's reliance on articles which were published after that date. Caraco says that the relevant date is October 29, 1996, one year before Novo filed its U.S. patent application. For the reasons that follow, the Court finds all articles published prior to October 29, 1996 are prior art under 35 U.S.C. §§ 102(b) and 103(a) and that articles published prior to October 29, 1997 are prior art under 35 U.S.C. §§ 102(a) and 103(a) unless Novo can

establish an earlier date of invention.

## II. FACTS

There are no material disputes with respect to the facts addressed in Novo's Memorandum. At the Court's request, each party submitted a timeline;<sup>1</sup> they are essentially the same.

Prior to June 27 1994 Dr. Peter Muller (Muller), a Novo employee, conceived of the idea of treating Type 2 diabetes through a combination therapy of repaglinide and metformin. On June 27, 1994 Muller proposed a study of this therapy and began collaborating with others in the employ of Novo to design a clinical study. A final study protocol was approved on March 23, 1995 and the clinical trial began on July 18, 1995. The study concluded on July 8, 1996 and Muller received the final results of the study on December 2, 1996. On October 29, 1997, Novo filed a United States patent application for combination therapy using repaglinide and metformin.

Prior to Novo's application a number of articles addressing combination therapy for Type 2 diabetes were published in academic journals. Among them were an article published by Dr. Arne Melander in September 1996 and an article published by Dr. Kohei Kaku in November 1996. The dispute between the parties is whether these articles were published before or after the relevant date for qualification as prior art.

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<sup>1</sup>See Appx. A.

### III. THE LAW

#### A.

An inventor is not eligible to obtain a patent if the claimed subject matter would have been obvious to one of ordinary skill in the art. 35 U.S.C. § 103(a) (section 103) states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Although section 103(a) requires a comparison between the claimed invention and the prior art, it does not define the scope and content of prior art that a court should consider. The Federal Circuit has defined prior art as “knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in the art.” Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1453 (Fed. Cir. 1984).

#### B.

To determine the knowledge that is available to a person of ordinary skill in the art, courts have looked to other sections of the Patent Act. In particular, courts have looked to 35 U.S.C. § 102 (section 102). In re Harry, 333 F.2d 920, 923 (C.C.P.A. 1964) (“Prior art’ referred to in section 103 includes . . . the patents, printed publications, public uses, and sales of paragraphs (a) and (b) of section 102.”); Oddzon Products, Inc. v. Just Toys, Inc., 122 F. 3d 1396, 1401-02 (Fed. Cir. 1997) (holding that

material included in section 102 (a), (b), (e), (f), and (g)<sup>2</sup> is prior art for purposes of section 103); Riverwood Int'l Corp. v. R.A. Jones & Co., 324 F.3d 1346, 1354 (Fed. Cir. 2003) (holding that section 103 “prior art” encompasses “at least the statutory material named in 35 U.S.C. § 102”). Section 102 states in part:

A person shall not be entitled to a patent unless –  
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or sale in this country, more than one year prior to the date of the application for patent in the United States.

Patents, publications, and uses are considered knowledge available to one skilled in the art and may qualify as prior art under either subsection (a) or (b) of section 102. However, before a court may consider the information contained in such sources, it must determine whether or not the information was available before the patent’s relevant date and, therefore, constitutes prior art.

### C.

In order to determine the relevant date for prior art, it is important to consider the two temporal requirements for the issuance of a patent: “(1) that the inventor was the first to invent and (2) that the inventor[s] filed their application in a timely manner.” PETER S. MENELL ET AL., FEDERAL JUDICIAL CENTER, PATENT CASE MANAGEMENT JUDICIAL GUIDE 11.3.4 (2009) (Patent Case Management). When faced with potential prior art, a court must determine the statute under which it will be considered and temporal requirement that the

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<sup>2</sup>Subsections (e), (f), and (g) of section 102 are not relevant to this analysis.

statute addresses.

1.

Both sections 102(a) and 103 seek to ensure that the inventor was the first to invent and, therefore, define a patent's relevant date in terms of the date of invention. 35 U.S.C. § 102(a) ("before the invention thereof"); § 103(a) ("at the time the invention was made"). Unless a patentee comes forward with evidence of an earlier date of invention, there is a presumption that the filing date of the patent application is the date of invention. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1577 (Fed. Cir. 1996). However, an inventor who exercises reasonable diligence in reducing an invention to practice may claim the date of conception as the invention date. Id. Under section 102(a) and 103 a patent, publication, or use does not qualify as prior art unless it was publicly available prior to the date of invention.

When an invention is conceived, diligently pursued, and reduced to practice in a foreign country, a patent holder only has a limited right to rely on the date of foreign conception rather than the date of filing the U.S. patent application. When an invention is made in a foreign nation that is a member of the World Trade Organization (WTO), the earliest allowable date of invention is twelve months after the United States became a member of the WTO on January 1, 1995, namely January 1, 1996. See 35 U.S.C. § 104.

2.

Unlike sections 102(a) and 103(a), section 102(b) seeks to ensure that an inventor files a patent application in a timely manner. In order to promptly expand the public's knowledge and to prevent inventors from extending the effective life of their

patent, any publication, use, or sale that is available to the public more than one year before the U.S. filing date constitutes prior art, regardless of the date of invention.

PATENT CASE MANAGEMENT 11.3.4.5. In other words, “[i]t presents a sort of statute of limitations . . . now one year, within which an inventor, even though he has made a patentable invention must act on penalty of loss of his right to patent. In re Foster, 343 F.2d 980, 987-88 (C.C.P.A. 1965).

When a party relies on section 102(b) in combination with section 103 to prove that a patent is invalid for obviousness, there is a potential for conflict between the one-year “critical date” under section 102(b) and the date of invention referred to in section 103. When such a conflict arises, the “critical date” of section 102(b) is controlling. Id. at 989; MANAGING PATENT CASES 11.3.5.3.2 (“Notwithstanding the test of §103, which measures obviousness as of the time of invention, §102(b) references can also apply in making §103 obviousness determinations, even though they are effective as of one year prior to the application filing date (and hence may postdate the time of invention).”) 2 DONALD S. CHISUM, CHISUM ON PATENTS §5.03[2][b] (2010) (“Because of the interaction between the obviousness requirement of Section 103 and the statutory bar provision of Section 102(b), all patents, publication, and public uses with an effective date of over one year prior to the inventor’s *application* may be considered in determining whether the invention is obvious.”).

In giving primacy to the “critical date” in section 102(b), the court in In re Foster focused on the role of public disclosure in creating a time bar and found that it was immaterial whether public disclosure described the claimed invention completely or merely provided sufficient information as to make the invention obvious:

First, as to principle, the purpose of [section 102(b)] has always been to require filing of the application within the prescribed period after the time the public came into possession of the invention, we cannot see that it makes any difference how it came into such possession, whether by a public use, a sale, a single patent or publication, or by combinations of one or more of the foregoing. In considering this principle we assume, of course, that by these means the invention has become obvious to that segment of the 'public' having ordinary skill in the art. Once this has happened, the purpose of the law is to give the inventor only a year within which to file and this would seem to be a liberal treatment.

Id. at 988. The court further held that "it follows that where the time-bar [of section 102(b)] is involved, the actual date of invention becomes irrelevant and it is not in accordance with either the letter or the principle of the law . . . to permit an applicant to dispose of a reference having a date more than one year prior to his filing date by proving his actual date of invention. Id. at 989.

### 3.

When a particular publication, use, or sale can be applied under either section 102(a) or (b), it qualifies as prior art if it meets either test. First, pursuant to section 102(b) (either alone or in combination with section 103), all publication, uses, and sales occurring more than one year before the filing date of a U.S. patent application constitute prior art, regardless of the actual invention date. Second, when a publication, use, or sale occurs between the one-year "critical date" and the U.S. filing date, it constitutes prior art under section 102(a) (either alone or in combination with section 103) unless the patent applicant can establish a date of invention that precedes the date that the art became public.

## **IV. APPLICATION**

Novo objects to the introduction of several articles that Caraco relies upon to prove obviousness. The two paradigm articles are the 1996 Melander article and the 1996 Kaku article.

### **A. The 1996 Melander Article**

The 1996 Melander article was published on September 13, 1996. Regardless of the actual invention date, Novo is time-barred under sections 102(b) and 103 from claiming that the article is not prior art. As stated above, Novo did not apply for the '358 patent in the United States until October 29, 1997. Thus the 1996 Melander article was published prior to the critical date of October 29, 1996. Therefore, it constitutes prior art under In re Foster, regardless of the actual date of invention.

### **B. The 1996 Kaku Article**

The 1996 Kaku article was published on November 12, 1996. Because the article was published after the critical date of October 29, 1996, section 102(b) is not applicable. However, the article was published before Novo filed the '358 patent application on October 29, 1997 and will constitute prior art under section 102(a) unless Novo can establish an earlier date of invention.

Novo says that Dr. Muller had conceived of the combination of repaglinide and metformin prior to June 27, 1994 when he proposed the Australian Study and that Novo worked with reasonable diligence to reduce the conception to practice. Because the invention was conceived, pursued, and reduced to practice in a foreign WTO member country, Novo says that the appropriate date of invention is January 1, 1996. Novo

bears the burden of proving the earlier date of invention. If Novo is successful in establishing an invention date of January 1, 1996, the 1996 Kaku article will not be considered prior art under section 102(a) or sections 102(a) and 103.<sup>3</sup> However, if Novo fails to establish the earlier invention date, the 1996 Kaku article will be considered prior art because it predated the filing of Novo's patent application.

Dated: June 9, 2010

S/Avern Cohn  
AVERN COHN  
UNITED STATES DISTRICT JUDGE

I hereby certify that a copy of the foregoing document was mailed to the attorneys of record on this date, June 9, 2010, by electronic and/or ordinary mail.

S/Julie Owens  
Case Manager, (313) 234-5160

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<sup>3</sup>Even if the 1996 Kaku article is not considered prior art under section 102(a) or sections 102(a) and 103, it may still constitute evidence of obviousness under the so-called "secondary consideration" of Near Simultaneous Invention. See 2 CHISUM, CHISUM ON PATENTS §5.05[7].